K013202

SECTION VI: 510(k) SUMMARY
[as required by section 807.92(c)]

OCT 2 3 2001

A. Submitter's Information:

Name:	Thomas Medical Products, Inc.
Address:	65 Great Valley Parkway Malvern, PA 19355
Telephone Number:	610.296.3000
Facsimile:	610.296.4591
Contact Person:	Tim Stoudt
Title:	Quality Assurance Engineering Manager
Date Submission Prepared:	September 17, 2001

B. Device Information:

Trade name:	Not assigned at the time of submission
Classification Name(s):	Catheter Introducer (21 CFR §870.1340), Vessel Dilator (21 CFR §870.1310), Percutaneous Catheter (21 CFR §870.1250)
Common or usual name(s):	6 French Braided Guiding Introducer

C. Legally marketed device to which equivalence is claimed:

Thomas Medical Products, Inc., Braided Guiding Introducer (K004026)

D. Description of the device:

The Thomas Medical Products Inc. 6 French Braided Guiding Introducer(s) are designed to provide a conduit to deliver diagnostic and therapeutic catheters to specific heart chambers and locations in the heart. The sheath may be used for percutaneous entry. Each 6 F Braided Guiding Introducer consists of the following: a sheath, a dilator, and a "J" tip guidewire.

In addition, a standard 12 cc syringe, a 18 gage XTW introducer needle, and a pre-dilator may also be packaged with the 6 F Braided Guiding Introducer Kit.

E. Intended use of the device:

The 6 F Braided Guiding Introducer is indicated for the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal perforation / puncture.

F. Summary of the technological characteristics of the device compared to the predicate device:

The technological characteristics of the device are the same as the those of the predicate device.

G. Substantial equivalence rationale:

The Thomas Medical Products Inc. 6F Braided Guiding Introducer has the same general intended use / indications for use and technological characteristics as other previously cleared devices. Therefore, based on these similarities, the Thomas Medical Products, Inc. 6F Braided Guiding Introducer is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2001

Mr. Tim Stoudt
Quality Assurance Engineering Manager
Thomas Medical Products, Inc.
65 Great Valley Parkway
Malvern, PA 19355

Re: K013202
6F Braided Guiding Introducer
Regulation Number: 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 11, 2001
Received: September 25, 2001

Dear Mr. Taufen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013202

Device Name: 6F Braided Guiding Introducer

Indications For Use:

For the percutaneous introduction of various types of cardiovascular catheters to all heart chambers, including the left atrium via transseptal perforation / puncture.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013202

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)